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December 07, 2004

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APPLICATION NUMBER: 60/515,481
FILING DATE: *October 29, 2003*
RELATED PCT APPLICATION NUMBER: PCT/US04/36416

Certified by



Jon W Dudas


Acting Under Secretary of Commerce
for Intellectual Property
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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No. **EL 706577820 US**

INVENTOR(S)					
Given Name (first and middle [if any])		Family Name or Surname		Residence (City and either State or Foreign Country)	
Kenneth J.		Ruchala		Madison, Wisconsin	
Additional inventors are being named on the <u>one</u> separately numbered sheets attached hereto					
TITLE OF THE INVENTION (500 characters max)					
EMBEDDED RADIOGRAPHIC INDEXING-PATIENT COUCH CONTRASTING DENSITY MARKERS					
Direct all correspondence to: CORRESPONDENCE ADDRESS					
<input checked="" type="checkbox"/> Customer Number:		20572		 20572 PATENT & TRADEMARK OFFICE	
OR					
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ENCLOSED APPLICATION PARTS (check all that apply)					
<input checked="" type="checkbox"/> Specification Number of Pages <u>8</u>		<input type="checkbox"/> CD(s), Number _____			
<input checked="" type="checkbox"/> Drawing(s) Number of Sheets <u>4</u>		<input checked="" type="checkbox"/> Other (specify) <u>Retn recpt postcard</u>			
<input type="checkbox"/> Application Date Sheet. See 37 CFR 1.76					
METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT					
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27.		FILING FEE Amount (\$)			
<input type="checkbox"/> A check or money order is enclosed to cover the filing fees.		<div style="border: 1px solid black; padding: 10px; width: fit-content; margin: auto;">\$80.00</div>			
<input checked="" type="checkbox"/> The Director is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number: <u>07-1509</u>					
<input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.					
The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.					
<input checked="" type="checkbox"/> No.					
<input type="checkbox"/> Yes, the name of the U.S. Government agency and the Government contract number are: _____					

Respectfully submitted,

[Page 1 of 2]

Date 10/29/2005

SIGNATURE

REGISTRATION NO. 41,606

TYPED or PRINTED NAME

William K. Baxter

(if appropriate)

Docket Number: 066744-0048TELEPHONE 414-273-3500**USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT**

This collection of information is required by 37 CFR 1.51. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop Provisional Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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 PTO
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PROVISIONAL APPLICATION COVER SHEET
Additional Pag

PTO/SB/16 (08-03)

Approved for use through 07/31/2006. OMB 0651-0032

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Docket Number 066744-0048

INVENTOR(S)/APPLICANT(S)		
Given Name (first and middle (if any))	Family or Surname	Residence (City and either State or Foreign Country)
Adam	Schloesser	Mount Horeb, Wisconsin
Eric	Schloesser	Mount Horeb, Wisconsin
David	Murray	Madison, Wisconsin

[Page 2 of 2]

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Number 2 of 2

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04772 U.S. PTO

PTO/SB/17 (10-03)

Approved for use through 07/31/2006. OMB 0651-0032

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FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$) 80.00

Complete if Known

Application Number
Filing Date 10/29/2003
First Named Inventor Kenneth J. Ruchala et al.
Examiner Name
Art Unit
Attorney Docket No. 066744-0048

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☒ Deposit Account:

Deposit Account Number 07-1509
Deposit Account Name GODFREY & KAHN, S.C.

The Director is authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☒ Credit any overpayments

☒ Charge any additional fee(s) or any underpayment of fee(s)

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FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description	Fee Paid
1001 770	2001 385	Utility filing fee	
1002 340	2002 170	Design filing fee	
1003 530	2003 265	Plant filing fee	
1004 770	2004 385	Reissue filing fee	
1005 160	2005 80	Provisional filing fee	80
SUBTOTAL (1)			(\$) 80.00

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims	Extra Claims	Fee from below	Fee Paid
Independent Claims	-20** =	X	
Multiple Dependent	-3** =	X	

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description
1202 18	2202 9	Claims in excess of 20
1201 86	2201 43	Independent claims in excess of 3
1203 290	2203 145	Multiple dependent claim, if not paid
1204 86	2204 43	** Reissue independent claims over original patent
1205 18	2205 9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) (\$)

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Small Entity

Fee Code (\$)	Fee Code (\$)	Fee Description	Fee Paid
1051 130	2051 65	Surcharge - late filing fee or oath	
1052 50	2052 25	Surcharge - late provisional filing fee or cover sheet	
1053 130	1053 130	Non-English specification	
1812 2,520	1812 2,520	For filing a request for <i>ex parte</i> reexamination	
1804 920*	1804 920*	Requesting publication of SIR prior to Examiner action	
1805 1,840*	1805 1,840*	Requesting publication of SIR after Examiner action	
1251 110	2251 55	Extension for reply within first month	
1252 420	2252 210	Extension for reply within second month	
1253 950	2253 475	Extension for reply within third month	
1254 1,480	2254 740	Extension for reply within fourth month	
1255 2,010	2255 1,005	Extension for reply within fifth month	
1401 330	2401 165	Notice of Appeal	
1402 330	2402 165	Filing a brief in support of an appeal	
1403 290	2403 145	Request for oral hearing	
1451 1,510	1451 1,510	Petition to institute a public use proceeding	
1452 110	2452 55	Petition to revive - unavoidable	
1453 1,330	2453 665	Petition to revive - unintentional	
1501 1,330	2501 665	Utility issue fee (or reissue)	
1502 480	2502 240	Design issue fee	
1503 640	2503 320	Plant issue fee	
1460 130	1460 130	Petitions to the Commissioner	
1807 50	1807 50	Processing fee under 37 CFR 1.17(q)	
1806 180	1806 180	Submission of Information Disclosure Stmt	
8021 40	8021 40	Recording each patent assignment per property (times number of properties)	
1809 770	2809 385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810 770	2810 385	For each additional invention to be examined (37 CFR 1.129(b))	
1801 770	2801 385	Request for Continued Examination (RCE)	
1802 900	1802 900	Request for expedited examination of a design application	

Other fee (specify)

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$)

SUBMITTED BY

(Complete if applicable)

Name (Print/Type) William K. Baxter Registration No. 41,606 Telephone 414-273-3500
Signature *William K. Baxter* Date 10/29/2003

758744

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**PROVISIONAL PATENT APPLICATION**

Inventors : Kenneth J. Ruchala, a citizen of the United States of America,
residing at 121 Richland Lane, Madison, Wisconsin 53705

Adam Schloesser, a citizen of the United States of America,
residing at 204 South 8th Street, Mount Horeb, Wisconsin 53572

Eric Schloesser, a citizen of the United States of America,
residing at 210 S Fifth Street, Mount Horeb, Wisconsin 53572

David Murray, a citizen of New Zealand,
residing at 1264 Deming Way, Apartment #102, Madison,
Wisconsin 53717

Assignee : TomoTherapy Incorporated

Title : EMBEDDED RADIOGRAPHIC INDEXING – PATIENT
COUCH CONTRASTING DENSITY MARKERS

Sheets of Drawings : 4


CERTIFICATION OF EXPRESS MAIL UNDER 37 C.F.R. § 1.10

Express Mail Mailing Number: EL 706577820 USDate of Deposit: October 29, 2003

I hereby certify that this application/correspondence attached hereto is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 on the date indicated above and is addressed to: Mail Stop Provisional Patent Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

William K. Baxter

(Typed or printed name of person mailing correspondence)


(Signature of person mailing correspondence)

William K. Baxter
Registration No. 41,606
GODFREY & KAHN, S.C.
780 North Water Street
Milwaukee, Wisconsin 53202
Tel.: 414-273-3500
Fax: 414-273-5198
Email: Wbaxter@gklaw.com

EMBEDDED RADIOGRAPHIC INDEXING – PATIENT COUCH CONTRASTING DENSITY MARKERS

BACKGROUND AND SUMMARY OF THE INVENTION

The present invention relates generally to radiographic indexing of a tomotherapy treatment table, and more particularly to embedding radiographic markers in a patient couch of a tomotherapy system for calibrating and positioning the top of the couch with a high degree of precision and accuracy.

A linear accelerator of a tomotherapy system provides the radiation for the therapy. A multi-leaf collimator concentrates the radiation into the beams which are applied to the tumor. Each beam is approximately one square centimeter in size. The multi-leaf collimator is mounted on the head of the linear accelerator which rotates on a gantry around the patient. The patient is immobilized on a treatment couch which comprises a tabletop and a base. The tomotherapy tabletop as well as other radiotherapy and diagnostic patient tables are able to move independently of the base in the lateral (x-axis) and/or longitudinal (y-axis) directions. The base is moveable in the vertical directions (z-axis). This allows the patient, who is lying on the tabletop, to be positioned to the desired x, y and z location.

Radiation therapy couches are conventionally and typically used to hold the patient in a substantially rigid position, while the patient is being exposed to a radiation source. In radiotherapy treatment of patients, it is imperative that the patient be held in a correct position relative to the radiotherapy machine in order to attain the expected treatment result without damaging healthy tissue outside of the treatment area. Therefore, there is a need for a radiographic indexing system embedded in the top of the patient couch for calibrating and

positioning the couch with a high degree of precision and accuracy. While the goal is to use this technology in radiotherapy tomotherapy, this invention could also be used for couches used for diagnostic imaging and in particular, radiotherapy simulation.

The present invention provides an integrated calibration and positioning means for a
5 radiotherapy system. The present invention involves embedding material for radiographic
referencing into the patient couch of the tomotherapy system. The material is preferably a
radiological marker or indexing material that has a density different from density of the couch
material, or a radio-frequency or magnetic contrasting matter - something that the imaging
system and detector of the tomotherapy system can detect, so that when scanned, with or without
10 a patient or phantom on it, the precise location of the patient couch in the x, y and z planes is
known. The material may also have the ability to be visually seen by the technician, doctor, or
physicist conducting the procedure. This is important so that the couch may be reconstructed,
alone or with a phantom on it, by the system software, providing a very good indication of where
the couch top is prior to treatment.

15 The present invention provides for calibrating the location and position of the couch, and
also for accurately positioning a patient on the couch. For example, aligning the couch with the
bore, detecting the scan plane, determining the slice-sensitivity profile for computed tomography
(CT) images, and aligning lasers with the virtual scan plane.

The present invention also provides methods to verify quality assurance (QA) and patient
20 procedures. For example, verifying the couch speed and/or position and couch-bore collision
avoidance.

In addition to the calibration and QA uses described above, the present invention may also be used for: (a) improving or simplifying the setup of the patient on the couch; (b) improving or simplifying the placement of patient fixation devices on the couch; and (c) identifying coordinate transformations between patient space and fixation-device space. For
5 example, the tomotherapy system could convert a set of patient adjustments detected in a CT image to proper translations or rotations on a given fixation device.

As mentioned above, the present invention comprises a marker or indexing matrix of material that is embedded or inlaid into the patient couch of the tomotherapy system. The inlaid marker or indexing matrix may be placed and spaced in any configuration in the couch. The
10 inlaid marker or indexing matrix may comprise embedded wire, voids and/or contrasting material. The present invention includes various styles and forms of markers and various configurations.

The marker or indexing matrix may be comprised of contrasting high or low density material in the form of solids (e.g. wire, pellets, balls, paste), liquids (e.g. column of water,
15 bubble-level, etc.), disjoint-solids (e.g. strings of marker beads) that are inlaid into or fixed onto the sides, top or bottom of the patient couch. These density "markers" can either be actual objects or the absence of objects (e.g. voids).

In one embodiment, the markers may be protrusions from the couch, allowing for patient fixation devices to be connected. In another embodiment, the markers may be flush with the
20 sides or surfaces of the couch. In yet another embodiment, the markers may be indentations or grooves in the couch.

The markers may come individually or in sets of two or three, or more, and potentially utilize sides and/or faces of the couch. The markers may be permanently fixed or removable from the couch, to minimize interference with dose delivery. The markers may be interchangeable with different sets or subsets utilized for different objectives.

5 In another embodiment, the markers may be magnetic, or include magnets or sensors that may be used for positioning patients and/or fixation devices.

In another embodiment, the markers may emit radio frequency (RF) signals which can be detected using RF sensitive detection devices.

10 In yet another embodiment, the markers may include lasers that can be used for any of the above purposes, including the positioning of patients and/or fixation devices on the couch, avoidance of couch collisions, system setup and calibration, etc.

15 The markers, including lasers, may send and/or receive signals with other fixtures in the room to detect changes in couch height or deformations in the couch, such as sagging. This information can be used to automatically, semi-automatically, or manually adjust the couch position before or during treatment procedures.

20 The markers may also be used for calibration and verification of couch speed, couch position and of the virtual iso-center. Treatment accuracy is maintained by aligning the linear accelerator's iso-center to a precise point within the patient. The iso-center is a single reference point in the x-y-z plane which serves to orient the radiation beams to the proper coordinates of the slices of the tumor in the patient.

In further embodiments, the present invention may comprise radiographic plugs, contrast inserts or resolution inserts that are inserted into cylindrical holes in the patient couch. The plugs or inserts would be used for calibrating the imaging system or dose delivery, and possibly positioning of the patient on the couch.

5 Various other features, objects, and advantages of the invention will be made apparent to those skilled in the art from the following detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective, cut-away view of a radiation therapy system providing for the acquisition of radiographic projections and for the generation of high energy radiation therapy beams and showing a patient couch for supporting a patient thereon;

10

FIG. 2 is a perspective view and detail of an embodiment of a radiographic marker inlay indexing grid embedded or inlaid into the patient couch;

FIG. 3 is a top plan view and detail of a radiographic marker inlay indexing grid embedded or inlaid into the patient couch; and

15 FIG. 4 is a cross-sectional view and detail of the patient couch of FIG. 3 taken along line E-E.

DETAILED DESCRIPTION OF THE INVENTION

Referring now to the drawings, FIG. 1 illustrates a radiation therapy machine (tomotherapy system) suitable for use with the present invention. The radiation therapy machine preferably includes a radio translucent table having a cantilevered top. The table top is received

20

within a bore of an annular housing of the radiation therapy machine with movement of the table along tracks extending along a longitudinal axis. The table is preferably disposed along a translation axis and may slide along that axis through the bore passing first the front surface and then the rear surface. The table is supported along guide tracks and moved by a motorized drive, such as is well known in the art, so that its position may be controlled by a computer as will be described. The table also includes an internal track assembly and elevator (not shown) to allow adjustment of the table top in a lateral axis translation and a vertical axis translation. Motion in the lateral and vertical directions are limited by the diameter of the bore. The radiation therapy machine further includes a computer having a display screen and user entry mouse and keyboard, well known in the art, that is connected to the radiation therapy machine to control motion of the table and to coordinate operation of the gantry together with the radiation source and x-ray source and to collect data from the linear array detector during a scan of a patient according to methods well known in the art.

FIG. 2 is a perspective view and detail of an embodiment of a radiographic marker inlay indexing grid embedded or inlaid into the patient couch of the tomotherapy system. In this embodiment, a wire inlay crosses latitudinally and longitudinally forming a matrix grid across the patient table. FIG. 2 shows a basic indexing grid, but the grid of the present invention would most likely be significantly more complex to achieve accurate resolution in three dimensions. The matrix of radiological material throughout the couch would preferably be three-dimensional material mounted in the couch that would allow couch indexing. For example, the Detail D of FIG. 2 shows a three-dimensional cross-hair as part of the matrix of marker material embedded in the couch. In addition, grids or reference points may also be used.

FIG. 3 is a top plan view and detail of the radiographic marker inlay indexing grid embedded or inlaid into the patient couch. Detail C shows the details of the indexing grid embedded in the couch.

FIG. 4 is a cross-sectional view and detail of the patient couch of FIG. 3 taken along line E-E showing the embedded radiographic markers in Detail F embedded into the top of the couch.

The radiological markers and/or indexing grid are preferably used for positional calibration of the patient couch.

In addition to the embodiments shown, the present invention may comprise radiographic plugs that are inserted into the couch that are used for calibrating the imaging system. The plugs would preferably have a density different than bone, tissue or water. The radiographic plugs would preferably be inserted into a row of cylindrical holes at the ends of the couch.

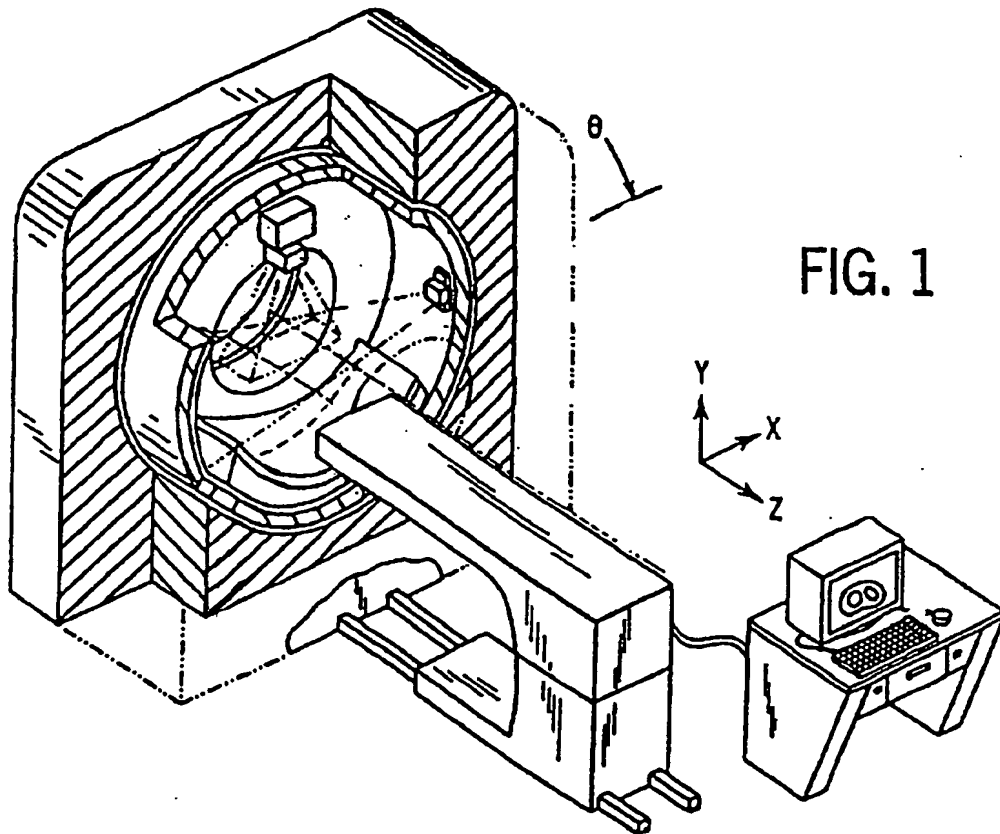
The plugs would generally be used to calibrate the imaging system. You would take an image of the couch and make sure that you see the plugs where you expect to see them. The plugs are preferably used for density or imaging calibration. The plugs may be the same or a different density from the couch material. The plugs are generally available from such manufacturers as Standard Imaging or Gammex.

In another embodiment, either contrast inserts or resolution inserts would be inserted into the cylindrical holes described above. The resolution inserts would preferably be a set of wires or holes (openings) based on some even or uneven spacing. These inserts would be used for calibrating the imaging system, and possibly positioning of the patient on the couch.

While the invention has been described with reference to preferred embodiments, those skilled in the art will appreciate that certain substitutions, alterations and omissions may be made to the embodiments without departing from the spirit of the invention. Accordingly, the foregoing description is meant to be exemplary only, and should not limit the scope of the

5 invention.

MW762368_2.DOC



WIRE CROSSES LATITUDINALLY AND
LONGITUDINALLY ACROSS PATIENT TABLE.

DETAIL D

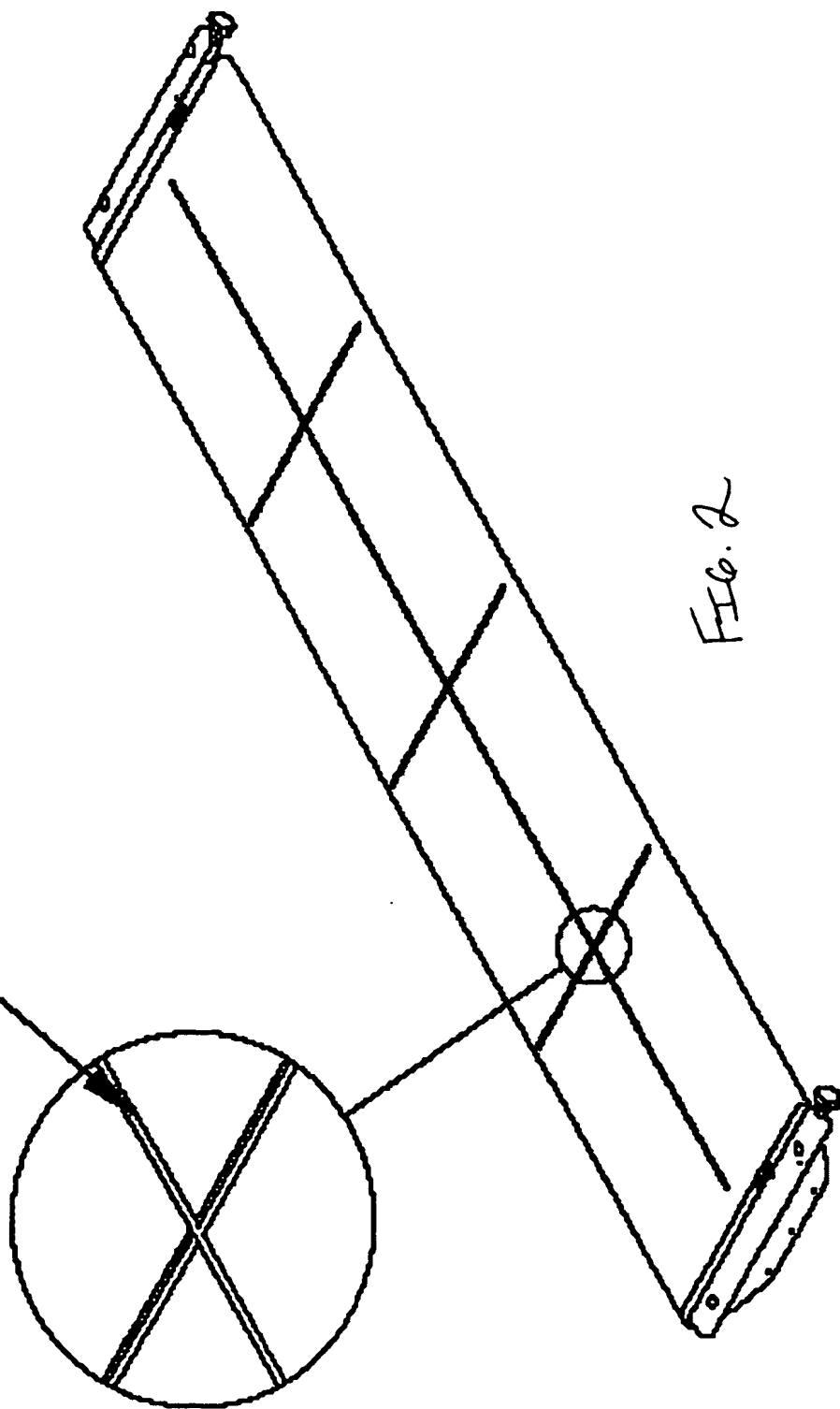
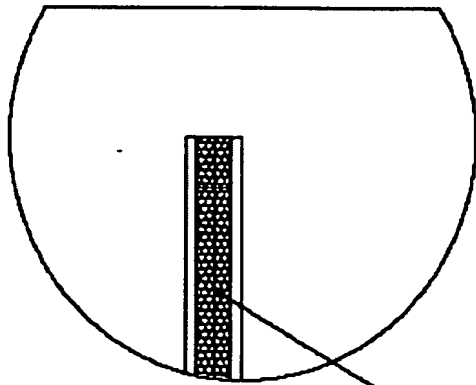


FIG. 2



DETAIL C

CONTRAST WITH SCANNED BODY STRUCTURE OF PATIENT.

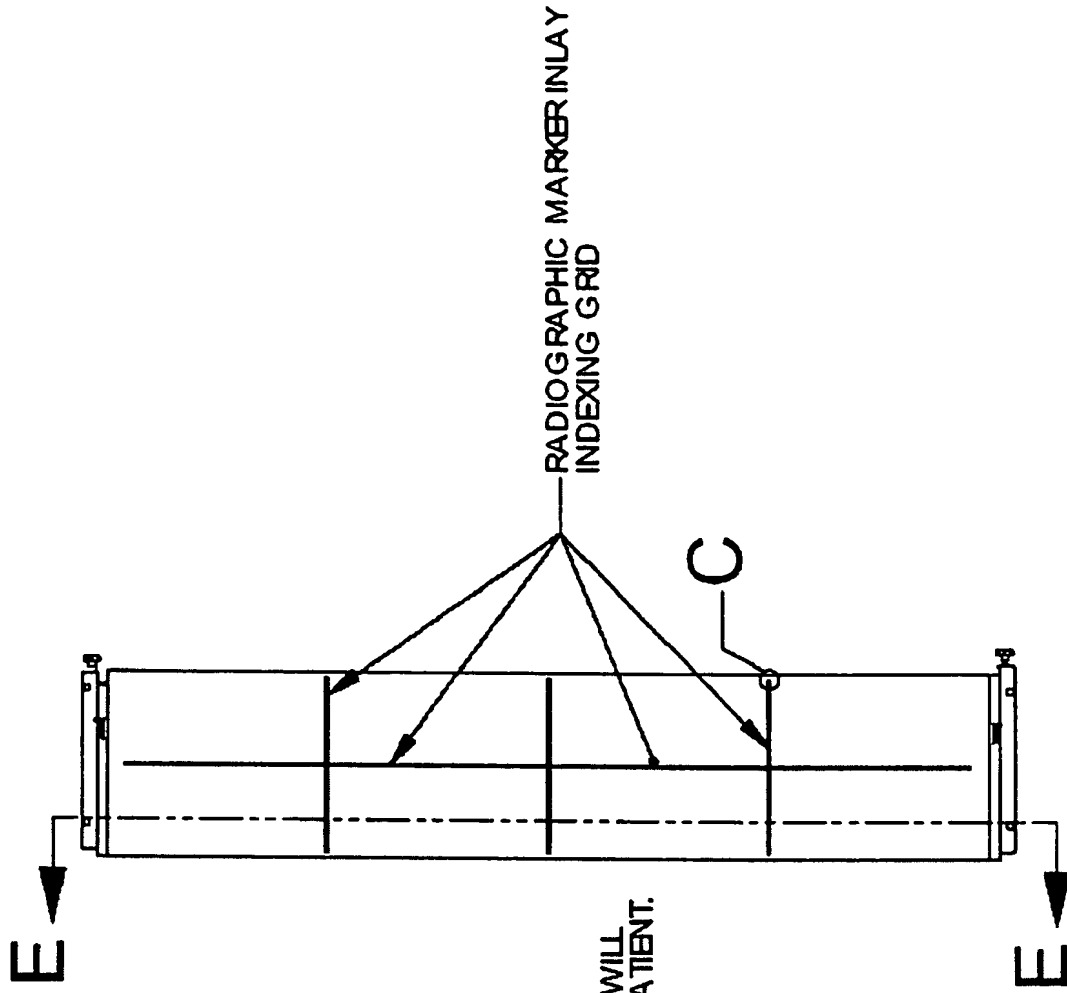


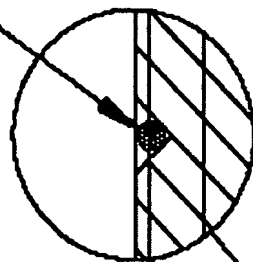
FIG. 3



RADIOGRAPHIC

EMBEDDED
MARKER

DETAIL F



SECTION E-E

Fig. 4

Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/US04/036416

International filing date: 29 October 2004 (29.10.2004)

Document type: Certified copy of priority document

Document details: Country/Office: US
Number: 60/515,481
Filing date: 29 October 2003 (29.10.2003)

Date of receipt at the International Bureau: 17 December 2004 (17.12.2004)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)



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